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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/845,731	04/30/2001	George Jackowski	2132.029	3804

21917 7590 11/25/2002

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EXAMINER
SMITH, CAROLYN L

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 11/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/845,731	JACKOWSKI ET AL.	
	Examiner	Art Unit	
	Carolyn L Smith	1631	

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-35 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-35 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicant is hereby notified that the required timing for the correction of drawings has changed. See the last 6 lines on the sheet which is attached titled "Attachment for PTO-948 (Rev. 03/01 or earlier)". It is noted that a PTO Form 948 is mailed herewith. Due to the above notification Applicant is required to submit drawing corrections within the time period set for responding to this Office action. Failure to respond to this requirement may result in abandonment of the instant application or a notice of a failure to fully respond to this Office action.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR § 1.821 (a)(1) and (a)(2). See for example, claims 1, 17, 18 and elsewhere. However, this application fails to comply with the requirements of 37 CFR § 1.821 through 1.825, because claims 1, 17, 18, 25, 29, 30, 34, and 35 lack SEQ ID NOs when citing a particular sequence. Instead of referring to a sequence with a letter name, such as ID RIHWESASLL in claim 17, applicants must follow the standard sequence rule under 37 CFR § 1.821(d) and refer to the sequence via its sequence identifier preceded by "SEQ ID NO". Applicant(s) are required to submit a computer readable form sequence listing, a paper copy, or CD-ROM with appropriate corrections, statements under 37 CFR § 1.821 (f) and (g). Applicant(s) are given the same response time regarding this failure to comply as that set forth to respond to this office action. Failure to respond to this requirement may result in abandonment of the instant application or a notice of a failure to fully respond to this Office Action.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-2, drawn to a biopolymer marker, classified in class 530, subclass 300.

II. Claims 3-9, drawn to a method of evidencing or categorizing at least one disease state, classified in class 436, subclass 173.

III. Claims 10-34, drawn to a diagnostic assay kit and process of identifying therapeutic avenues, classified in class 422, subclass 61; class 435, subclass 7.1; and class 530, subclass 387.1. If this Group is elected then the **TWO** below summarized specie elections requirement are also required.

IV. Group 35, drawn to a process for regulating a disease state by controlling presence or absence of a biopolymer, classified in class 514, subclass 2.

Specie Election Requirements for Group III:

This application contains claims directed to the following **TWO** sets of patentably distinct species of the claimed invention:

FIRST specie election requirement for Group III:

Specie A: a biochemical material which is a monoclonal antibody

Specie B: a biochemical material which is a polyclonal antibody

Specie C: a biochemical material which is a non-antibody

SECOND *additional* specie election requirement for Group III:

Specie D: diagnosis

Specie E: determination of risk assessment

Specie F: identification of therapeutic avenues

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, the claims in Group III are generic to the above two sets of species. This distinctness or independence of a monoclonal antibody versus a polyclonal antibody versus a non-antibody (for first specie set) as well as diagnosis versus determination of risk assessment versus identification of therapeutic avenues is because these species are directed to different chemical and entity types regarding the critical limitations therein. For the monoclonal antibody specie, the critical feature is a monoclonal antibody. For the polyclonal antibody specie, the critical feature is a polyclonal antibody. For the non-antibody specie, the critical feature is a non-antibody. For the diagnosis specie, the critical element is an analysis to determine the presence of the biopolymer. For the determination of risk assessment specie, the critical feature is an analysis to determine risks. For the identification of therapeutic avenues specie, the critical feature is discovering methods of treatment. Please note that the last three species have different goals, and steps for achieving those goals, which make them patentably distinct. The completely separate chemical and entity types of the invention species are often separately characterized and published in literature, thus adding to the burden is all species were examined together. Also, processing that may connect two species does not prevent them from being considered distinct because enough processing can result in the production of any

composition from another composition as long as the processing is not limited in occurrences such as subtractions, additions, and enzymatic actions. Thus, the six species are independent and/or distinct for restriction purposes.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

These groups are distinct, each from the other because of the following reasons:

Inventions in Groups I, II, III, and IV are related as product and the process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that

product (MPEP § 806.05(h)). In the instant case the biopolymer of Group I may be utilized in distinct usages as needed in Group II for a method of evidencing or categorizing at least one disease state, in a diagnostic assay kit and process for identifying therapeutic avenues as in Group III, in a process for regulating a disease state as in Group IV, or alternatively, in preparing T cells. All of these usages are distinct as requiring distinct and different functions thereof without overlapping search due to different subject matter. This lack of overlapping searches documents the undue search burden if they were searched together.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement may be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and

1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (703) 308-6043. The examiner can normally be reached Monday through Friday from 8 A.M. to 4:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

November 18, 2002

Ardin H. Marschel

ARDIN H. MARSCHEL
PRIMARY EXAMINER